

Serial No. 10/027,401
Docket No. 0081.01

In the Claims:

Please amend claims 1, 4, 8, 30 and 40-42 as indicated below. Please cancel claim 7 without prejudice. Currently amended claims are presented with markings to indicate the changes made, wherein ~~strike through~~ is used to designate deleted subject matter and underlining is used to designate added subject matter.

1. (Currently Amended) A process for the production of polymeric microparticles comprising dissolving a polymer in a halogen-free solvent that is at least partially water-miscible to form a polymer solution; adding a non-water soluble active agent to the polymer solution to form a drug phase contained in a vessel; adding a predetermined amount of an aqueous surfactant phase to the vessel containing the drug phase with mixing, said predetermined amount being sufficient to (i) result in a volume fraction of the surfactant phase of at least 0.60, and (ii) provide that the surfactant phase becomes the continuous phase and extraction medium in order to extract an amount of said solvent from said drug phase such that a suspension of microparticles is produced upon addition of the surfactant phase to the drug phase without requiring removal of the solvent from the vessel.

2. (Original) A process according to claim 1 further comprising removing the solvent.

3. (Original) A process according to claim 2 wherein the solvent is removed by washing, filtration, vacuum, or evaporation.

4. (Currently Amended) A process according to claim 1 wherein the solvent has a water solubility of at least ~~1.5—40~~ 1.5 to 40 wt% in water.

5. (Original) A process according to claim 4 wherein the solvent solubility is at least 5 wt% in water.

6. (Original) A process according to claim 5 wherein the solvent solubility is at least 10 wt% in water.

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7. (Canceled).

8. (Currently Amended) A process according to claim 1 wherein the volume fraction of the surfactant phase is ~~0.65—0.75~~ 0.65 to 0.75.

9. (Original) A process according to claim 1 further comprising adding a water-miscible co-solvent to the surfactant phase wherein said polymer solvent is soluble in said co-solvent and said polymer is not soluble in said co-solvent.

10. (Original) A process according to claim 8 wherein said co-solvent is selected from the group consisting of alcohols, polyethylene glycol, and ethers.

11. (Original) A process according to claim 9 wherein the co-solvent is selected from the group consisting of ethanol, methanol, isopropyl alcohol, and polyethylene glycol.

12. (Original) A process according to claim 1 further comprising adding a buffer to the drug solution.

13. (Original) A process according to claim 1 further comprising adding a buffer to the surfactant phase.

14. (Original) A process according to claim 13 wherein the polymer is not soluble in the surfactant phase.

15. (Original) process according to claim 1 wherein the microparticles comprise microcapsules.

16. (Original) A process according to claim 1 wherein the microparticles comprise microsponges.

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17. (Original) A process according to claim 1 wherein the microparticles comprise microspheres.
18. (Original) A process according to claim 1 wherein the non-water soluble drug is dissolved in the polymer solution to form the drug phase.
19. (Original) A process according to claim 18 further comprising adding an aqueous buffer solution to the drug phase.
20. (Original) A process according to claim 19 further comprising adding an aqueous surfactant phase to the drug phase slowly over a period of at least 1 minute.
21. (Original) A process according to claim 20 wherein the resulting microparticles comprise microcapsules with the hydrophobic drug embedded within the polymeric wall of the microcapsule.
22. (Original) A process according to claim 21 further comprising microspheres.
23. (Original) A process according to claim 22 comprising up to 30 wt% of a mixture of microsponges and microcapsules and the remainder comprising microspheres.
24. (Original) A process according to claim 19 further comprising adding the aqueous surfactant phase to the drug phase immediately.
25. (Original) A process according to claim 18 or 24 wherein the resulting microparticles comprise at least 80 wt% microspheres.
26. (Original) A process according to claim 25 wherein the resulting microparticles further comprise up to 20 wt% microcapsules comprising the hydrophobic drug embedded within the polymeric wall of the microcapsule.

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27. (Original) A process according to claim 1 wherein a suspension of the hydrophobic drug is added to the polymer solution.

28. (Original) A process according to claim 27 wherein the resulting microparticles comprise microcapsules wherein the active agent is contained in the microcapsule core in a suspension.

29. (Original) A process according to claim 1 further comprising adding a viscosity modifier to the aqueous surfactant phase.

30. (Currently Amended) A process according to claim 29 comprising ~~5~~ 5 to 50 wt% of the viscosity modifier.

31. (Original) A process according to claim 30 wherein the viscosity modifier is selected from the group consisting of glycerol or polyethylene glycol.

32. (Original) The process according to claim 13, wherein the buffered solution is selected from the group consisting of a phosphate buffer solution, a citrate buffer solution and a tris(hydroxymethyl)aminomethane solution.

33. (Original) A process according to claim 1 wherein the polymer is selected from the group consisting of polyamides, polyanhydrides, polyesters, polyorthoesters, polyacetates, polylactones, and polyorthocarbonates.

34. (Original) A process according to claim 33 wherein the polymer is selected from the group consisting of polyesters of α -, β - and γ -hydroxycarboxylic acids, or block copolymers of polyesters of α -, β - and γ -hydroxycarboxylic acids and linear or star poly(ethylene glycols).

35. (Original) A process according to claim 34 wherein the polymer comprises a poly lactide co-glycolide polymer.

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36. (Original) A process according to claim 1 wherein the partially water-miscible solvent is selected from the group consisting of acetone, ethanol, alkyl acetates, alkyl formates, triacetin, triethyl citrate, and alkyl lactates or mixtures thereof.

37. (Original) A process according to claim 36 wherein the solvent is selected from the group consisting of ethanol, acetone, methyl acetate, ethyl acetate, propyl acetate, isopropyl acetate, butyl acetate, methyl formate, ethyl formate, propyl formate, isopropyl formate, butyl formate, triacetin, triethyl citrate, methyl lactate, ethyl lactate or mixtures thereof.

38. (Original) A process according to claim 1 wherein the surfactant is a non-ionic surfactant.

39. (Original) A process according to claim 1 wherein $\delta_{\text{polymer solvent}} - \delta_{\text{aqueous phase}}$ is less than zero.

40. (Currently Amended) A process according to claim 39 wherein $\delta_{\text{polymer solvent}} - \delta_{\text{aqueous phase}}$ is within ~~0 to -15~~ 0 to -15.

41. (Currently Amended) A process according to claim 1 wherein the volume ratio of the polymer phase : surfactant phase is within the range ~~1:2 to 1:30~~ 1:2 to 1:30.

~~41~~ 42. (Currently Amended) Microparticles produced by the process according to any one of claims 1, 4, 7, 9, 29, 33, 39, 40 or 41 ~~or 39-41~~.

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